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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,575	11/16/2001	Johann Eibl	A34720-PCT-USA-A	7871

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EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,575	EIBL, JOHANN	
	Examiner	Art Unit	
	Susan Hanley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 99-104* is/are pending in the application.

4a) Of the above claim(s) *3-98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 99-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's reply and amendment filed 10/7/05 are acknowledged.

Election/Restrictions

This application contains claims drawn to an invention nonelected with traverse in the response filed 1/2/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 2 and 99-104 are pending.

Response to Arguments

Applicant's arguments filed 10/7/05 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 2 and 99-103 stand rejected under 35 U.S.C. 103(a) as being unpatentable over MacPhee et al. (US 6,054,122) in view of Burnouf (Colloque INSERM (1989) 175: 373-81) and Racanelli et al. (US 5,254,536).

Applicant argues that the Examiner has not established a *prima facie* case of obviousness because there is no suggestion or motivation to combine the three references since none of them teach the addition of serpins or the separate vial inactivation of serpins. Burnouf does not disclose serpins and Racenelli states that there is no synergistic effect resulting from the combination of thrombin and rPAI-I and that the disclosed data shows that the effect of PAI-1 and thrombin together is no greater that the additive effect of the two agents administered individually. Applicant asserts that the ordinary artisan would not

be motivated to add serpins to the composition of MacPhee, which contains thrombin, because Racanelli shows no addition benefit by adding serpins to a composition containing thrombin. Applicant further argues that neither of the secondary references suggests or teaches viral inactivation of serpins separate from other agents. Applicant argues that Burnoff does not say that serpins should be treated separately. Applicant asserts that Burnoff only states that different techniques are needed and that inactivation treatments can be performed on the final product with other agent present. Applicant concludes that the ordinary artisan would not be motivated to single out serpins to be treated separately from other active agents based on Burnoff because they would not know if the serpin inactivation should occur during purification or inactivated as a final product. Applicant argues that MacPhee discloses a foam which is different that the instantly claimed liquid or solid tissue sealant. Applicant argues that a person of ordinary skill would not be motivated to combine the cited references to produce a solid or liquid since MacPhee's composition is a foam or to add a serpin to the composition of MacPhee and to virally inactive the serpin separate from other agents.

Applicant further argues that the references do not teach the limitations of the present invention because since neither Racanelli nor Burnouf do not specifically state that serpins must be separately inactivated from other agents and thus do not meet the limitation that requires such. Applicant argues that MacPhee teaches the use of $CaCl_2$ as a drying agent and does not disclose the use of $CaCl_2$ to solidify the allogenic provision matrix and that $CaCl_2$ is added to the already dry composition to "accelerate the speed of fibrin formation.

Responding to Applicant's argument regarding what the references allegedly fail to teach in relationship to the limitations of the present invention, the standard for meeting the claim limitations for an obviousness rejection is that the combination of references teaches all of the limitations. Burnoff teaches the purification from blood and separate viral inactivation of several components of the claimed invention including fibrinogen, thrombin as a prothrombin complex and a serpin, alpha 1-antitrypsin. Burnouf states that not all treatments are efficacious for inactivating all pathogenic human blood-borne

viruses and the purification procedure influences the virus elimination step (p. 373, first paragraph). Burnoff specifically discloses the separate purification and viral inactivation of several blood-derived proteins, including a serpin and fibrinogen and prothrombin complex. The ordinary artisan would have realized from Burnoff that a serpin can be depleted of viruses separately from other blood components and that this it advantageous purify and virally inactivate blood proteins due to the significantly different purification/viral inactivation schemes.

Responding to Applicant's argument that MacPhee discloses a foam composition, the foam composition is one of several embodiments for the disclosed tissue sealant (TS). MacPhee et al. disclose a fibrin sealant bandage wherein dry, virally inactive agents are disposed in layers on a backing (col. 2 to col. 28, bridging). Furthermore, MacPhee discloses that the components for fibrin sealants are also traditionally disposed in separate containers and reconstituted upon (col. 4, lines 7-21). Furthermore, MacPhee teaches an embodiment wherein the fibrinogen components and the thrombin agents are separately purified to solid form and separately virally inactivated(col. 10, lines 56-68 to col. 11, lines 1-9). This is considered to meet the limitation of a solid composition. Responding to Applicant's argument that MacPhee teaches the use of $CaCl_2$ as a drying agent and does not disclose the use of $CaCl_2$ to solidify the allogenic provision matrix and that $CaCl_2$ is added to the already dry composition to "accelerate the speed of fibrin formation", a drying agent is equivalent to a dehydrating agent because the purpose of both is to remove water. The removal of water naturally results in solidification. Although MacPhee does not state if water is present in his composition, the application of a drying agent will remove any water molecules present. $CaCl_2$ has many intrinsic properties. It is a dehydrating agent and serves as a cofactor for transglutaminase. Intrinsic properties and their actions on a substrate do not detract from the claimed limitation of a dehydrating agent that is met by the disclosure of $CaCl_2$.

Responding to Applicant's argument that there is no motivation to add a serpin to the composition of MacPhee since there is no synergistic effect for combined thrombin and rPAI-I and that Racanelli's data shows that the effect of the combination of PAI-1 and thrombin is no different that the

two agents administered individually, Racanelli clearly provide motivation to add PAI-1 to a TS comprising thrombin because the serpin markedly improves the performance of thrombin by itself. At two hours, the combination of PAI-1 and thrombin decreased blood loss to 0.9 compared to 1.3 when using thrombin by itself. This data provides the ordinary artisan with motivation to add PAI-1 to a TS composition comprising thrombin because it improves the blood clotting performance compared to thrombin alone. It is immaterial that the combination is not synergistic. The data in Table I of Racanelli shows that adding PAI-1 to thrombin decreases fibrinolysis which is the express need stated by MacPhee (col. 26, lines 30-35).

Responding to Applicant's assertion that Burnoff only states that different techniques are needed and that inactivation treatments can be performed on the final product with other agent present, Applicant is taking Burnouf's statement out of context. Burnouf states: "Various virus inactivation treatment have been used: some are applied during the purification process while others can, in some instances, be performed on the final product." The "final product" alluded to by Burnoff means the final product of a purification scheme to isolate the blood component from its source. For support of this statement, see p. 377 wherein Burnouf describes purification and viral inactivation methods for *individual blood proteins*. Burnoff is not directed to the combination of blood proteins with each other or other products. It is not clear in Burnouf's disclosure where the mention of "other agents" is stated or implied.

Responding to Applicant's argument that the ordinary artisan would not be motivated to single out serpins to be treated separately from other active agents based on Burnoff because they would not know if the serpin inactivation should occur during purification or inactivated as a final product, Burnouf clearly states that "The final alpha 1-antitrypsin fraction is then pasteurized" (p. 3775, lines 5-6 at the ATT-1 purification description). The remainder of the description is devoted to dealing with aggregates that might form during pasteurization. It is unclear why the ordinary artisan would find this confusing.

Responding to Applicant's argues that a person of ordinary skill would not be motivated to combine the cited references to produce a solid or liquid since MacPhee's composition is a foam, as stated

supra, a foam tissue sealant composition is just one of MacPhee's embodiments. MacPhee discloses solid compositions as part of bandages as well as solid agents in separate vials. Thus, the ordinary artisan would find motivation in MacPhee to make a solid TS composition.

In response to applicant's argument that there is no suggestion to combine the references because none of them teach the addition of serpins or the separate vial inactivation of serpins, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to add a serpin to the composition of MacPhee was discussed *supra* and said motivation is justified because the addition of the serpin to thrombin clearly increases the clotting ability of thrombin by itself and MacPhee expressly states that it is desirable to add compounds that inhibit the breakdown of the fibrin clot (col. 26, lines 30-35). Racanelli clearly demonstrate that a serpin fulfills this need.

The combined references clearly provide motivation to the ordinary artisan to separately virally inactivate the serpin from the other agents of the claimed composition. MacPhee discloses that the components for fibrin sealants are also traditionally disposed in separate containers: (1) fibrinogen concentrate witch contains fibronectin, Factor XIII and von Willebrand factor; (2) dried human or bovine thrombin; and (3) calcium ions. The components are mixed together at the time of use and applied to a tissue (col. 4, lines 7-21). Thus, the separate disposition of TS components was well known in the art. Furthermore, MacPhee teaches an embodiment wherein the fibrinogen components and the thrombin agents are separately purified and separately virally inactivated(col. 10, lines 56-68 to col. 11, lines 1-9). Also, MacPhee teaches that the TS composition can be supplemented by other factors that enhance the TS efficacy, including a serpin (col. 12, line 37). These supplements can be added to the fibrinogen, the thrombin and/or the water component(s) before they are mixed to form the TS. Alternatively, the

supplements(s) can be added to the components as they are being mixed to form the TS (col. 21, lines 37-43). Thus, MacPhee clearly discloses that the components of the disclosed TS are separately purified and separately virally inactivated. Additionally, the ordinary artisan would have realized from the disclosure by MacPhee that supplements for the TS composition are prepared separately and can be combined with one or the other TS components or can be kept is a separate container until needed for use. Additionally, MacPhee stresses the need to virally deplete all components of the TS composition: "When used on human patients, the components are most preferably pathogen-inactivated, purified components derived from human sources" (col. 26, lines 9-20). Therefore, MacPhee provides motivation to add supplements, such as compounds that inhibit fibrinolysis, to the TS composition and that said components are separately purified, separately virally inactivated and can be kept separately from the other TS components or can be added to said other TS components.

The combined disclosures by MacPhee and Racanelli show the desirability of adding a serpin to a TS composition, that the components of the TS composition are obtained and separately purified from likely sources and the TS components are separately virally inactivated after said purification. The disclosure by Burnouf supports MacPhee because Burnouf discloses separate methods of purifying and virally decontaminating fibrinogen, prothrombin complex, serpin alpha 1-antitrypsin and factor IX (p. 377-338). The ordinary artisan would have known from Burnouf that *for any given blood protein, the purification procedure influences the virus elimination step* (p. 373, first paragraph). This is clearly exemplified by the comparison of clear differences between the purification/viral inactivation procedures for fibrinogen and serpin alpha 1-antitrypsin (p. 377-378).

Thus, the combined references clearly connect the addition of a serpin to the TS composition of MacPhee and that virally inactivation methods are protein dependent. The ordinary artisan would have been motivated to inactivate a serpin separately from the thrombin and fibrin agents in the TS of MacPhee since MacPhee teaches separate inactivation of components and Burnouf teaches that blood proteins, including serpins, are best purified and virally inactivated in separate procedures.

Claims 1, 2 and 99-104 stand rejected under 35 U.S.C. 103(a) as being unpatentable over MacPhee et al. (US 6,054,122) in view of Burnouf (Colloque INSERM (1989) 175: 373-81) and Racanelli et al. (US 5,254,536) as applied to claims 1, 2 and 99-103 above, and further in view of Stroetmann (US 4,442,655) which was cited in the IDS of 11/16/01.

Applicant argues that a person of ordinary skill in the art would not be motivated to combine MacPhee, Burnouf and Racanelli since the references do not teach serpins or separate inactivation of serpins or the use of a dehydrating agent to solidify the matrix. Applicants further argue that Stroetmann does not provide a suggestion or motivation to virally inactivate serpins separately from the other agents and Stroetmann teaches that the final product is sterilized after packing, which Applicant asserts implies that all of the agents are present. Applicant asserts that Stroetmann is directed to sterilization and not viral inactivation and that Stroetmann does not disclose dehydrating agents to solidify the provisional matrix. Applicant argues that Stroetmann is direct to the use of organic solvents to increase the solubility of the active agents in solution and that Stroetmann uses freeze-frying and not dehydrating agents to dry the composition. Applicant argues that a person of ordinary skill in the art would not be motivated to add an organic solvent to the composition of MacPhee to solidify the provision matrix by the use of dehydrating agents.

In response to applicant's argument that there is no suggestion to combine the references because none of them teach the addition of serpins or the separate vial inactivation of serpins, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to add a serpin to the composition of MacPhee was discussed *supra* and said motivation is justified because the addition of the serpin to thrombin clearly

increases the clotting ability of thrombin by itself and MacPhee expressly state desirable to add compounds that inhibit the breakdown of the fibrin clot (col. 26, lines 30-35). Racanelli clearly demonstrate that a serpin fulfills this need.

The combined references clearly provide motivation to the ordinary artisan to separately virally inactivate the serpin from the other agents of the claimed composition. MacPhee discloses that the components for fibrin sealants are also traditionally disposed in separate containers: (1) fibrinogen concentrate witch contains fibronectin, Factor XIII and von Willebrand factor; (2) dried human or bovine thrombin; and (3) calcium ions. The components are mixed together at the time of use and applied to a tissue (col. 4, lines 7-21). Thus, the separate disposition of TS components was well known in the art. Furthermore, MacPhee teaches an embodiment wherein the fibrinogen components and the thrombin agents are separately purified and separately virally inactivated(col. 10, lines 56-68 to col. 11, lines 1-9). Furthermore, MacPhee teaches that the TS composition can be supplemented by other factors that enhance the TS efficacy, including, serpin alpha 1-antityrpsin (col. 12, line 37). These supplements can be added to the fibrinogen, the thrombin and/or the water component(s) before they are mixed to form the TS. Alternatively, the supplements(s) can be added to the components as they are being mixed to form the TS (col. 21, lines 37-43). Thus, MacPhee clearly discloses that the components of the disclosed TS are separately purified and separately virally inactivated. Additionally, the ordinary artisan would have realized from the disclosure by MacPhee that supplements for the TS composition are prepared separately and can be combined with one or the other TS components or can be kept is a separate container until needed for use. Additionally, MacPhee stresses the need to virally deplete all components of the TS composition: "When used on human patients, the components are most preferably pathogen-inactivated, purified components derived from human sources" (col. 26, lines 9-20). Therefore, MacPhee provides motivation to add supplements, such as compounds that inhibit fibrinolysis, to the TS composition and that said components are separately purified, separately virally inactivated and can be kept separately from the other TS components or can be added to said other TS components.

The combined disclosures by MacPhee and Racanelli show the desirability of adding a serpin to a TS composition and that the components of the TS composition are obtained and purified from likely sources and separately virally inactivated after said purification. The disclosure by Burnouf supports MacPhee because Burnouf discloses separate methods of purifying and virally decontaminating fibrinogen, prothrombin complex, alpha 1-antitrypsin and factor IX (p. 377-338). The ordinary artisan would have known from Burnouf that *for any given blood protein, the purification procedure influences the virus elimination step* (p. 373, first paragraph). This is clearly exemplified by the comparison of clear differences between the purification/viral inactivation procedures for fibrinogen and serpin alpha 1-antitrypsin (p. 377-378).

Thus, the combined references clearly connect the addition of a serpin to the TS composition of MacPhee and that virally inactivation methods are protein dependent. The ordinary artisan would have been motivated to inactivate a serpin separately from the thrombin and fibrin agents in the TS of MacPhee since MacPhee teaches separate inactivation of components and Burnouf teaches that blood proteins are best purified and virally inactivated in separate procedures.

Responding to Applicant's argument that Stroetmann does not provide a suggestion or motivation to virally inactivate serpins separately from the other agents, that Stroetmann teaches that the final product is sterilized after packing and that Stroetmann teaches sterilization and not viral inactivation, Stroetmann was not relied upon to teach or provide motivation for these aspects of the instant invention. Further, sterilization of the combined agents that have previously been virally inactivated does not teach away from the present invention. Responding to Applicant's assertions that Stroetmann does not disclose dehydrating agents to solidify the provisional matrix, that Stroetmann is directed to the use of organic solvents to increase the solubility of the active agents in solution and that Stroetmann uses freeze-frying and not dehydrating agents to dry the composition, organic solvents have a number of intrinsic properties. they can serve as drying agents as well as solubilizing agents. Their dual role does not detract from Streetman's disclosure. Regarding Streetman's use of freeze-drying step, the

instant claims have open language "comprising" and further drying steps are permissible in the disclosure of the prior art citation. Responding to Applicant's argument that a person of ordinary skill in the art would not be motivated to add an organic solvent to the composition of MacPhee to solidify the provision matrix by the use of dehydrating agents, the ordinary artisan would have recognized from Stroetmann that the use of organic solvents and cross-linking of the TS composition would be advantageous because such treatment makes dry preparation having greater mechanical strength.

Claims 1, 2 and 99-104 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Stroetmann (US 4,442,655), which was cited in the IDS of 11/16/01, in view of MacPhee et al. (US 6,054,122), Burnouf (Colloque INSERM (1989) 175: 373-81) and Racanelli et al. (US 5,254,536).

Applicant argues that their previous arguments directed to the rejection over MacPhee in view of Burnouf and Racanelli, in further view of Stroetmann, apply equally to the rejection over Stroetmann in view of MacPhee, Burnouf, and Racanelli. Applicant asserts that the cited references do not provide any suggestion or motivation to virally inactivate serpins separately from other active agents, and do not teach all of the limitations of the present invention.

Responding to Applicant's generalized argument, the limitations and motivation to combine the references to give the present invention are restated:

Stroetmann et al. disclose a dry preparation comprising a fibrin sealant, wherein an aqueous solution comprising fibrinogen and salts is combined with a drying agent such as ethylene glycol. The fibrinogen can be isolated and lyophilized (col. 3, lines 50-55 and col. 4, lines 15-20). This dry preparation can be enriched with collagen, thrombin and fibrinolysis inhibitors (col. 6, lines 21-68). It is also desirable to crosslink the dry preparation with factor XIII to increase its mechanical strength. Stroetmann et al. also teach that the dry preparation should be sterilized (col. 11, lines 5-10).

Stroetmann et al. do not teach that all of the active agents are from an allogenic source (claims 2 and 104), the composition comprises a serpin that does not inhibit elastase or collagenase (as in instant claims 1, 100-102) or that said serpin is sterilized separately from the other agents (as in instant claim 1).

The disclosures by MacPhee et al., Burnouf and Racanelli et al. are discussed *supra*, as well as in the previous Office action.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the dry preparation taught by Stroetmann et al. by using the active agents from an allogenic source and adding a serpin that does not inhibit elastase or collagenase, wherein said serpin is sterilized separately from the other agents. The ordinary artisan would have been motivated to add PAI-1 to the composition taught by Stroetmann et al. because Stroetmann et al. expressly disclosed the desirability of adding a fibrinolytic agent to their composition to prevent premature clot degradation. The fibrinolytic agent disclosed by Racanelli et al., recombinant PAI-1, counteracts excessive fibrinolysis, thus meeting the express need of Stroetmann et al. The ordinary artisan would have had a reasonable expectation that PAI-1 would successfully work in the composition of Stroetmann et al. because Racanelli et al. teach that the combination of PAI-1, fibrinogen, thrombin and collagen makes an effective tissue sealant.

The ordinary artisan would have been motivated to sterilize the PAI-1 separately from the other active agents and to package said agents separately because Burnouf teaches that the isolation and viral inactivation methods for each of the claimed components from a human blood source should be done separately because each active substance has different requirements for purification and viral inactivation. The ordinary artisan would have had a reasonable expectation that PAI-1 could be successfully isolated and virally inactivated separate from the other active agents because Burnouf teaches how to accomplish this.

The ordinary artisan would have been motivated to make the dry preparation taught by Stroetmann et al. from allogenic sources because MacPhee et al. disclose that the use of an allogenic source reduces adverse immune reaction to the preparation. The ordinary artisan would have had a

reasonable expectation that the dry preparation taught by Stroetmann et al. could be made from allogenic sources because MacPhee et al. and Burnouf teach the isolation of the various active agents from human blood.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

JEAN C. WITZ
PRIMARY EXAMINER

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).